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NOTICE OF ALLOWANCE AND FEE(S) DUE

31013

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03/15/2010

KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT 1177 AVENUE OF THE AMERICAS NEW YORK, NY 10036 EXAMINER

BIANCHI, KRISTIN A

ART UNIT PAPER NUMBER

1626

DATE MAILED: 03/15/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,153	04/05/2006	Robert Jordan	056440-1402	9124

TITLE OF INVENTION: COMPOUNDS, COMPOSITIONS, AND METHODS FOR TREATMENT AND PREVENTION OF ORTHOPOXVIRUS

INFECTIONS AND ASSOCIATED DISEASES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	06/15/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

(571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 31013 7590 03/15/2010 Certificate of Mailing or Transmission KRAMER LEVIN NAFTALIS & FRANKEL LLP I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. INTELLECTUAL PROPERTY DEPARTMENT 1177 AVENUE OF THE AMERICAS NEW YORK, NY 10036 (Depositor's name (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/561,153 04/05/2006 Robert Jordan 056440-1402 9124 TITLE OF INVENTION: COMPOUNDS, COMPOSITIONS, AND METHODS FOR TREATMENT AND PREVENTION OF ORTHOPOXVIRUS INFECTIONS AND ASSOCIATED DISEASES APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1510 \$300 \$0 \$1810 06/15/2010 **EXAMINER** ART UNIT CLASS-SUBCLASS BIANCHI, KRISTIN A 1626 514-410000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number ______ (enclose an extra copy of this fo Advance Order - # of Copies _ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/561,153	04/05/2006	Robert Jordan	056440-1402	9124		
31013 75	31013 7590 03/15/2010			EXAMINER		
KRAMER LEVI	N NAFTALIS & FR	BIANCHI, KRISTIN A				
	PROPERTY DEPART	CMENT	ART UNIT	PAPER NUMBER		
1177 AVENUE OF THE AMERICAS NEW YORK, NY 10036			1626			

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 650 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 650 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
	 10/561,153	JORDAN ET AL.	
Notice of Allowability	Examiner	Art Unit	
	KRISTIN BIANCHI	1626	
The MAILING DATE of this communication appeal claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIOF the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in or other appropriate communication is supplication is supplication.	n this application. If not included unication will be mailed in due cours	
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2. ☑ The allowed claim(s) is/are <u>1-15 and 20-22</u> .			
 Acknowledgment is made of a claim for foreign priority ur All b)	e been received. be been received in Application cuments have been receive of this communication to file IENT of this application.	on No d in this national stage application freshed and the stage application from the stage application from the stage application from the stage and the stage are ply complying with the requirents.	nents
INFORMAL PATENT APPLICATION (PTO-152) which give 5. CORRECTED DRAWINGS (as "replacement sheets") must	es reason(s) why the oath o at be submitted.	r declaration is deficient.	2 01
(a) ☐ including changes required by the Notice of Draftspers	•	w (PTO-948) attached	
1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in to 6. DEPOSIT OF and/or INFORMATION about the depo	s Amendment / Comment on to .84(c)) should be written on to the header according to 37 CF	he drawings in the front (not the back) R 1.121(d).	
 Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 12/16/2009 	5.	formal Patent Application ummary (PTO-413), /Mail Date Amendment/Comment	
 Examiner's Comment Regarding Requirement for Deposit of Biological Material 	8. ⊠ Examiner's 9. □ Other	Statement of Reasons for Allowanc	e

Application/Control Number: 10/561,153 Page 2

Art Unit: 1626

DETAILED ACTION

Claims 1-15 and 20-22 are pending in the instant application. Claims 16-19 and 23-45 have been cancelled by way of examiner's amendment. Claims 1-15 and 20-22 are allowed.

Information Disclosure Statement

The information disclosure statement filed on December 16, 2009 has been considered and a signed copy of form 1449 is enclosed herewith.

Response to Arguments/Remarks

The arguments/remarks filed on January 11, 2010 have been fully considered. In regards to the 35 U.S.C. 112, first paragraph, rejection of claims 1, 2, 4-15, and 20-22, Applicant argues (and presents Exhibits 1-5) that the state of the art is replete with examples supporting the feasibility of the CPE assay for testing and identification of novel selective inhibitors of orthopoxviral infections which demonstrate potency and selectivity in *vitro* and further anti-viral efficacy in *vivo*. This argument (along with Exhibits 1-5) has been found to be fully persuasive and the 35 U.S.C. 112, first paragraph, rejection has been withdrawn.

Election/Restrictions

It is noted that upon further consideration, Groups II and III have been rejoined with Group I. Therefore, the subject matter of claims 1-15 and 20-22 has been searched and examined in its entirety.

EXAMINER'S AMENDMENT

Application/Control Number: 10/561,153 Page 3

Art Unit: 1626

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The claims have been amended as follows: claims 16-19 and 23-45 have been cancelled.

REASONS FOR ALLOWANCE

The methods of the instant claims are novel and non-obvious over the prior art because of the structural limitations of the compounds which are used in the methods (i.e., an amide group is bonded directly to the nitrogen atom of the polycyclic ring structure). The closest prior art is US Patent No. 4,061,763 which discloses compounds of Structure I (column 1) which have pharmaceutical utility (i.e., abstract). The compounds disclosed in US Patent No. 4,061,763 do not fall within the scope of the compounds used in the instant claims nor are they obvious variants. It is noted that the method of using the compounds disclosed in US Patent No. 4,061,763 (i.e., claim 4) also does not fall within the scope of the methods of the instant claims nor is it an obvious variant.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Art Unit: 1626

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/ Primary Examiner, Art Unit 1626 Kristin Bianchi Examiner Art Unit 1626
